Client/Matter: 016795-0282906

REMARKS

Reconsideration and allowance of the above-identified Application in view of the above amendments and the following remarks are respectfully requested.

Claims 1-25 are pending in the Application. Claim 25 has been added. Claims 1-24 have been amended merely to correct minor clerical errors. The amendments to the claims are not in any way intended to limit the subject matter recited therein.

Claim Objections

Claims 3 and 24 were objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form. Accordingly, Applicants have amended claim 3 to depend from claim 1 and to recite "A formulation according to claim 1, further comprising water." Therefore, Applicant respectfully submits that claim 3 is now written in proper dependent form and respectfully requests that the objection to claim 3 be withdrawn.

Claim 24 has been amended to recite "A method according to claim 22, further comprising performing a hair treatment procedure to the hairy area of the skin and/or the scalp after the composition is applied to the hairy area of the skin and/or the scalp." By this amendment, claim 24 is further limited by the additional limitation "performing a hair treatment procedure to the hairy area of the skin and/or the scalp after the composition is applied to the hairy area of the skin and/or the scalp." Therefore, Applicant respectfully submits that claim 24 is in proper dependent form and respectfully requests that the objection to claim 24 be withdrawn.

Claim Rejections – 35 USC § 112

Claims 3, 12 and 18-20 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claim 3 has been amended to recite "A formulation according to claim 1, further comprising water." Therefore, claim 3 is further clarified.

Claim 12 has been amended to depend from claim 2. Claim 12 recites "A formulation according to claim 2, wherein said thickener is white petroleum." One of ordinary skill in the art would understand the terminology "white petroleum" as being equivalent to "white petrolatum." Attached herewith, as exhibit A, is a definition of petrolatum and various other appellations for the same substance. Therefore, Applicant respectfully submits that claim 12 is perfectly clear.

VANDELL -- 09/942,672 Client/Matter: 016795-0282906

Claim 19 has been amended to recite "A formulation according to claim 1, wherein said formulation is a lotion." By this amendment the word "emulsion" has been deleted and replaced by the word "formulation." By this amendment, Applicant has further clarified the claim language.

Claim 20 has been amended to recite "A method of desensitizing the scalp prior to a hair treatment, comprising: applying a topical anesthetic containing composition to the scalp prior to the hair treatment; and allowing the composition to remain on the scalp enough time to desensitize the treated area, wherein the topical anesthetic containing composition contains a therapeutically effective amount of a topical anesthetic." By this amendment, Applicant has further clarified the claim language.

Therefore, Applicant respectfully submits that claims 3, 12 and 18-20 are in full compliance with § 112, second paragraph. Thus, Applicant respectfully requests that the rejection of claims 3, 12 and 18-20 under § 112, second paragraph be withdrawn.

Claim Rejections – 35 USC § 102

Claims 20 and 22-24 were rejected under 35 U.S.C. § 102(b) as being anticipated by Bass (U.S. Patent No. 6,066,676).

The Examiner contends that Bass teaches each and every limitation of claims 20 and 22-24. Applicant respectfully traverses this rejection for at least the following reasons.

Claim 20 recites "A method of desensitizing the scalp prior to a hair treatment, comprising: applying a topical anesthetic containing composition to the scalp prior to applying the hair treatment; and allowing the composition to remain on the scalp enough time to desensitize the treated area, wherein the topical anesthetic containing composition contains a therapeutically effective amount of a topical anesthetic."

Claim 22 recites "A method of desensitizing a hairy area of the skin and/or the scalp comprising: applying a topical anesthetic containing composition to the hairy area of the skin and/or the scalp prior to applying a hair treatment; permitting said composition to remain on the hairy area of the skin and/or the scalp thereby desensitizing the hairy area of the skin and/or the scalp; and removing said composition from the hairy area of the skin and/or the scalp." By applying a topical-anesthetic containing composition to the scalp and/or a hairy area of the skin prior to applying a hair treatment, the pain, for example, that may be engendered by the hair treatment can be reduced or alleviated.

Client/Matter: 016795-0282906

In contrast, Bass merely discloses a method for applying a composition (containing an antibiotic medication, an anti-inflammatory and an antihistamine) to the skin of a human patient to impart an anaesthetizing effect to the patient for the purpose of treating problems or disorders of the nervous system of the patient (see col. 1, lines 12-45 in Bass). In Bass' Example I in column 3, the composition is rubbed into a scalp at night and removed each morning. According to Bass, hair growth was observed following this procedure. Therefore, the composition of Bass is not applied to the scalp prior to applying a hair treatment but merely applied to grow hair. Consequently, Bass does not disclose, teach or suggest, *interalia*, "applying a topical anesthetic containing composition to the scalp prior to applying the hair treatment," as recited in claim 20 or "applying a topical anesthetic containing composition to the hairy area of the skin and/or the scalp prior to applying the hair treatment," as recited in claim 22.

Therefore, Applicant respectfully submits that claims 20 and 22, and claims 23 and 24 which depend from claim 22, are patentable. Thus, Applicant respectfully requests that the rejection of claims 20 and 22-24 under § 102(b) over Bass be withdrawn.

Claim Rejections – 35 USC § 103

Claims 1-19 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kaplan (U.S. Patent No. 4,052,513) in view of Durbak et al. (U.S. Patent No. 4,241,048).

Claim 1 recites, inter-alia, "A formulation for desensitizing skin and hair follicles comprising: a therapeutically effective amount of a topical anesthetic; a solubilizer for solubilizing said topical anesthetic; homopolymers; copolymers; and plant extract oils. By applying to the skin, for example the scalp, the formulation of claim 1, the skin (e.g., scalp) is desensitized, thus allowing, for example, to perform other procedures to the skin or scalp.

The Examiner concedes that Kaplan does not teach copolymers and plant extract oils recited in claim 1 and claim 21. The Examiner, however, contends that Durbak et al. teaches using PVP/hexadecane copolymer as a crystal growth suppressing agent and teaches plant oils such as eucalyptus oil as a counterirritant and coconut oil as a liquid carrier/emollient and thus contends that it would have been obvious to one of ordinary skill in the art to modify the compositions of Kaplan to employ PVP/hexadecane copolymer and to employ plant oils as suggested by Durbak et al. Applicant respectfully traverses this rejection for at least the following reasons.

VANDELL -- 09/942,672 Client/Matter: 016795-0282906

Durbak et al. merely discloses a composition containing powdered benzocaine suspended in an anhydrous carrier (hydrocarbon oil) and containing a co-polymer of vinylpyrrolidone and an alpha-olefin (PVP-hexadecene copolymer) to suppress crystal growth of benzocaine (see, abstract and col. 1, lines 40-45 in Durbak et al.). Durbak does not disclose, teach or suggest a solubilizer is used to dissolve benzocaine as Durbak is merely concerned about inhibiting crystallization of benzocaine.

Furthermore, there is no suggestion in Kaplan that benzocaine can be suspended in an organic oil and crystal growth in benzocaine prevented by adding a co-polymer (vinylpyrrolidone). In fact, Kaplan teaches away from suspending benzocaine in an oil. Kaplan specifically teaches dissolving benzocaine in an ester (such as diethyl sebacate), adding an emulsifier agent (a nonionic surfactant) to form a mixture, which mixture is then added to a water base solution. According to Kaplan, benzocaine is only very slightly soluble in water and attempts to solubilize benzocaine in water using various surface active agents have been made but the resulting preparations were generally found unstable with the benzocaine crystallizing (see col. 1, lines 15-25 in Kaplan). To circumvent these problems, Kaplan uses an ester to dissolve the benzocaine and a surfactant is added as an emulsifying agent before mixing with water.

Consequently, one of ordinary skill in the art would not have been motivated to modify the composition of Kaplan to employ the plant oils of Durbak et al. to suspend benzocaine because Kaplan is concerned about forming a <u>water based emulsion</u> which can "carry" benzocaine <u>not</u> an <u>oil based</u> composition.

Therefore, neither Kaplan nor Durbak et al., alone or in combination, disclose, teach or suggest a composition as recited in claim 1 or claim 21.

Therefore, Applicant respectfully submits that claims 1 and 21, and claims 2-19 which depend directly or indirectly from claim 1, are patentable. Thus, Applicant respectfully requests that the rejection of claims 1-19 and 21 under § 103(a) over the combination of Kaplan and Durbak et al. be withdrawn.

Claims 1, 3-5, 8-11, 13-19 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over GB 1 574 302 (hereinafter "GB '302") in view of Durbak et al. (U.S. Patent No. 4,241,048). Applicant respectfully traverses this rejection for at least the following reasons.

Client/Matter: 016795-0282906

The Examiner concedes that GB '302 does not teach the claimed copolymers and plant oils. The Examiner, however, contends that Durbak et al. teaches using PVP/hexadecane copolymer as a crystal growth suppressing agent and teaches plant oils such as eucalyptus oil as a counterirritant and coconut oil as a liquid carrier/emollient and thus contends that it would have been obvious to one of ordinary skill in the art to modify the compositions of GB '302 to employ PVP/hexadecane copolymer and to employ plant oils as suggested by Durbak et al. Applicant respectfully traverses this rejection for at least the following reasons.

Durbak et al. merely discloses a composition containing powdered benzocaine suspended in an anhydrous carrier (hydrocarbon oil) and containing a co-polymer of vinylpyrrolidone and an alpha-olefin (PVP-hexadecene copolymer) to suppress crystal growth of benzocaine (see, abstract and col. 1, lines 40-45 in Durbak et al.). Durbak does not disclose, teach or suggest a solubilizer is used to dissolve benzocaine as Durbak is merely concerned about inhibiting crystallization of benzocaine.

Furthermore, there is no suggestion in GB '302 that benzocaine can be suspended in an organic oil and crystal growth in benzocaine prevented by adding a co-polymer (vinylpyrrolidone). In fact, GB '302 teaches away from suspending benzocaine in an oil.

GB '302 teaches a benzocaine composition that contains a <u>water-miscible alcohol</u> in which the benzocaine is soluble, a <u>water-miscible glycol</u> in which the benzocaine is soluble and <u>water</u>. This composition can be sprayed as an aerosol. GB '302 does <u>not</u> disclose, teach or suggest a composition in which benzocaine is dissolved in a solubilizer and carried in <u>oil</u> as GB '302 is merely concerned about forming a composition in which benzocaine is dissolvable in <u>water</u> to form a sprayable solution.

According to GB '302, benzocaine is only very slightly soluble in water and solvents other than water have been used but the resulting preparations were generally found unstable with the benzocaine crystallizing (see lines 10-20 in GB '302). To circumvent these problems GB '302 uses a water-miscible alcohol and a water-miscible glycol to dissolve the benzocaine before mixing with water.

Consequently, one of ordinary skill in the art would not have been motivated to modify the composition of GB '302 to employ the plant oils of Durbak et al. to suspend benzocaine because GB '302 is concerned about forming a <u>water based sprayable solution</u> which can "carry" benzocaine <u>not</u> an <u>oil based</u> composition.

VANDELL -- 09/942,672 Client/Matter: 016795-0282906

Therefore, neither GB '302 nor Durbak et al., alone or in combination, disclose, teach or suggest a composition as recited in claim 1 or claim 21.

Therefore, Applicant respectfully submits that claims 1 and 21, and claims 3-5, 8-11, and 13-19 which depend directly or indirectly from claim 1, are patentable. Thus, Applicant respectfully requests that the rejection of claims 1, 3-5, 8-11, 13-19 and 21 under § 103(a) over the combination of GB '302 and Durbak et al. be withdrawn.

Claims 6 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over GB 1 574 302 (hereinafter "GB '302") in view of Durbak et al. (U.S. Patent No. 4,241,048) and further in view of Kaplan (U.S. Patent No. 4,052,513). Applicant respectfully traverses this rejection for at least the following reasons.

Claims 6 and 7 depend from claim 1. Therefore, for at least the reasons presented above with regard to claim 1, neither GB '302 nor Durbak et al., alone or in combination, disclose, teach or suggest the subject matter recited in claims 6 and 7.

Kaplan does not overcome the deficiencies noted above in the combination of GB '302 and Durbak. As stated above, Kaplan teaches dissolving benzocaine in an ester (such as diethyl sebacate), adding an emulsifier agent (a nonionic surfactant) to form a mixture, which mixture is then added to a water base solution. According to Kaplan, benzocaine is only very slightly soluble in water and attempts to solubilize benzocaine in water using various surface active agents have been made but the resulting preparations were generally found unstable with the benzocaine crystallizing (see col. 1, lines 15-25 in Kaplan). To circumvent these problems, Kaplan uses an ester to dissolve the benzocaine and a surfactant is added as an emulsifying agent before mixing with water. Kaplan is concerned about forming a water based emulsion which can "carry" benzocaine not an oil based composition. Kaplan does not teach or suggest that benzocaine can be suspended in an organic oil and crystal growth in benzocaine prevented by adding a co-polymer (vinylpyrrolidone).

Therefore, none of GB '302, Durbak et al. or Kaplan, alone or in combination, disclose, teach or suggest the subject matter recited in claims 6 and 7.

Therefore, Applicant respectfully submits that claims 6 and 7 are patentable and respectfully requests that the rejection of claims 6 and 7 under § 103(a) over the combination of GB '302, Durbak et al and Kaplan be withdrawn.

Client/Matter: 016795-0282906

Claim 25 has been added. Support for the claim language may be found throughout the initial disclosure. For example, one ordinary skill in the art would appreciate that benzocaine, lidocaine, and prolocaine belong to the caine family of chemicals.

Claim 25 depends from claim 20. Therefore, for at least the reasons presented above with respect to claim 20, Applicant respectfully submits that claim 25 is patentable.

CONCLUSION

In view of the foregoing, the claims are now in form for allowance, and such action is hereby solicited. If any point remains in issue which the Examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in a condition for allowance and a Notice to that effect is earnestly solicited.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

PILSBURY WINTHROP LLP

JACK S. BARUFK

Reg. No. 37087

Tel. No. (703) 905-2012 Fax No. 703 905-2500

JSB/KG

P.O. Box 10500 McLean, VA 22102 (703) 905-2000

EXHIBIT-A



pet·ro·la·tum

n: a neutral unctuous substance that is practically odorless and tasteless and is insoluble in water, that is obtained from petroleum and differs chemically from paraffin wax in containing unsaturated hydrocarbons or naphthenes as well as alkanes, and that is produced in several forms: as a: a yellowish to light amber semisolid mass used chiefly as a base for ointments and cosmetics, as a protective dressing, and in lubricating greases called also petroleum jelly, yellow petrolatum b: a white or faintly yellowish mass obtained by decolorizing yellow petrolatum and used similarly to it - called also petroleum jelly, white petrolatum, white petroleum jelly.

pe-tra-'lāt-am, -'lät-

Published under license with Merriam-Webster, Incorporated. © 1997-2004.

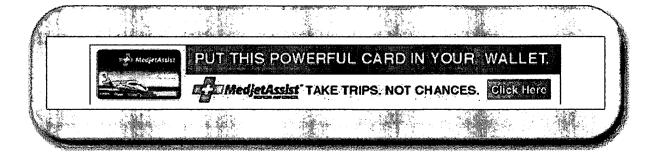
Medical Dictionary





Emergency Center Conditions & Diseases

Mentai Health Health Companies Medicare Sites



Sports dinjury Store

Insurance Companies Drug Search Men's Health

*/ast*onurse